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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/048,185	06/17/2002	Pascual Perez	34934-PCT-USA 072667.0180	2915
21003	7590	06/14/2006	EXAMINER ROBINSON, KEITH O NEAL	
BAKER & BOTTS 30 ROCKEFELLER PLAZA 44TH FLOOR NEW YORK, NY 10112			ART UNIT 1638	PAPER NUMBER

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/048,185

Applicant(s)

PEREZ ET AL.

Examiner

Keith O. Robinson, Ph.D.

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. The amendment of claim 18, the cancellation of claims 1-17 and the addition of new claims 20-27, filed March 22, 2006, have been received and entered in full. Those rejections or objections not specifically addressed in this Office Action are withdrawn in view of Applicant's amendments.

Claims 18-27 are pending.

Response to Arguments

2. Applicant's amendments and arguments, see 'REMARKS', page 5, paragraph # 1, filed March 22, 2006, with respect to the 35 USC § 112, second paragraph rejection of claim 18 on page 2 of the Office Action mailed September 23, 2005 have been fully considered and is persuasive. The rejection has been withdrawn.

Claim Rejections - 35 USC § 112, first paragraph - Enablement

3. Claims 18-19 remain rejected and new claims 20-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection is repeated for the reasons of record as set forth in the Office Action mailed September 23, 2005, as applied to claims 1-3, 5-8, 10, 12, 14-15 and 18-19 (see pages 3-6). Applicant's arguments filed March 22, 2006 have been fully considered but they are not persuasive.

Applicant argues the claims, as amended, are fully enabled because the use of maize genotypes other than those specified (A188 and Hi-II) in the specification merely involves routine crossing of a first "elite" maize line, unsuited for transformation, to a second, more easily transformable, cell line to generate a hybrid (see page 6, 2nd and 3rd paragraphs of 'REMARKS' filed March 22, 2006).

This is not persuasive. It would require undue trial and error experimentation for one skilled in the art to screen literally thousands of "elite" maize lines crossed with a second more easily transformable line to determine which, if any, would produce an isotransgenic maize line. The specification lacks guidance regarding the broad genus of "elite" maize lines and easily transformable lines.

Applicant argues that a list of suitable elite and transformable maize lines does not have to be included in the specification because a patent need not teach what is well known in the art (see page 6, 4th paragraph of 'REMARKS' filed March 22, 2006).

This is not persuasive. As stated in the Office Action mailed September 23, 2005 on pages 3-4, there is no evidence that other lines can be used in the invention as claimed. In addition, the claims are not limited to hybrids which have either A188 or Hi-II as one parent.

Applicant argues that the disclosed markers and method of analysis in the instant specification is enabling and that the references cited by the Examiner in a previous Office Action is contrary to the Examiner's interpretation (see page 7 of 'REMARKS' filed March 22, 2006).

This is not persuasive. The references were cited to show the unpredictability in using markers in the discrimination of related genomes. Regardless of Applicant's interpretation of the references, they do teach unpredictability. For example, as stated in a previous Office Action mailed June 24, 2004 on page 8, Staub et al demonstrates that marker systems differ in their use across populations, species and genera and their efficiency in the detection of polymorphisms. Though Welsh et al teach that "AP-PCR will work with most genome and species", Applicant only discloses the use of RFLP and has not provided any evidence of any other methods for analyzing and comparing genomes of transformed plants in the instant specification. Applicant is reminded that Welsh et al was cited to demonstrate the unpredictability inherent in identifying genomic sequences in the absence of a recitation of highly stringent conditions. Finally, Applicant has failed to provide any evidence showing that the references cited by the Examiner are not sound nor has Applicant provided support by fact or evidence to overcome the references cited.

Applicant's arguments regarding the number of backcrosses are persuasive (see page 8, 1st paragraph to page 9, lines 1-5 of 'REMARKS' filed March 22, 2006); however, these arguments do not overcome the claim rejections under 35 USC § 112, first paragraph with regard to enablement.

Claim Rejections - 35 USC § 112, first paragraph – Written Description

4. Claims 18-19 remain rejected and new claims 20-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in

Art Unit: 1638

such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office Action mailed September 23, 2005, as applied to claims 1-3, 5-8, 10, 12, 14-15 and 18-19 (see pages 6-7). Applicant's arguments filed March 22, 2006 have been fully considered but they are not persuasive.

Applicant argues that the molecular markers and marker assay techniques are described (see page 9, paragraph # 3 to page 12 of 'REMARKS' filed March 22, 2006).

This is not persuasive. The Examiner acknowledges that the molecular markers and marker assay techniques are described; however, as stated in the previous Office Action mailed September 23, 2005 the rejection was based on the fact that the single exemplified species of transformed maize plants with A188 as one parent, is not representative of the broadly claimed genus of any maize genotypes (see page 7, 2nd paragraph).

Claim Rejections - 35 USC § 102

5. Claim 19 remains rejected and new claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Ragot et al (Techniques et utilisations des marqueurs moléculaires; Montpellier (France) 29-31 mars 1994; Ed. INRA, Paris 1995 (Les Colloques, n72; pages 45-56). The rejection is repeated for the reasons of record as set forth in the Office Action mailed September 23, 2005 (see pages 8-9). Applicant's arguments filed March 22, 2006 have been fully considered but are not persuasive.

Applicant argues that the plants disclosed by Ragot et al cannot be like the claimed plants because Ragot et al use backcrossing and the Examiner allegedly stated that no amount of backcrossing will generate a truly isotransgenic plant (see page 12, paragraph # 5 to page 13 of 'REMARKS' filed March 22, 2006).

This is not persuasive. The Examiner refers Applicant to *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, **if the process of making the product fails to distinguish the two products**. In addition, the Examiner refers Applicant to *In re Best*, 195 USPQ 430, 433 (CCPA 1997), which teaches that **where the prior art product seems to be identical to the claimed product**, except that the prior art is silent as to a particularly claimed characteristic or property, then **the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention**.

Applicant has not provided evidence that the prior art would neither anticipate nor render obvious the claimed invention nor is the claimed invention distinguished from the prior art.

Furthermore, the Examiner has withdrawn his arguments regarding backcrossing as stated on page 4, 2nd paragraph of this Office Action.

Claim Rejections - 35 USC § 103

6. Claims 18-19 remain rejected and new claims 20-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishida et al (Nature Biotechnology 14: 745-

Art Unit: 1638

750, June 1996), in view of Does et al (Plant Mol. Biol. 17: 151-153, 1991), Hiei et al (Plant J. 6(2): 271-282, 1994), Armstrong et al (Theor. Appl. Genet. 84: 755-762, 1992) and Ragot et al (Techniques et utilisations des marqueurs moleculaires; Montpellier (France) 29-31 mars 1994; Ed. INRA, Paris 1995 (Les Colloques, n72; pages 45-56), as stated on pages 9-10 of the last Office Action for claims 1-3, 5-8, 10, 12, 14, 15, 18 and 19.

Applicant argues that *prima facie* obviousness has not been established because the selection step specified in claim 18, step b distinguishes the present invention from the combination of references cited by the Examiner (see page 14, 3rd full paragraph of 'REMARKS' filed March 22, 2006).

This is not persuasive. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference, nor is it that the claimed invention must be expressly suggested in any one or all the references. The test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to Applicant's arguments against the references individually (see page 14, last two lines to page 16, lines 1-4 of 'REMARKS' filed March 22, 2006), one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208

USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Finally, the instant claim scope is not commensurate with Applicant's evidence of unexpected results. Applicant only provides evidence of hybrids which have either A188 or Hi-II as one parent. In contrast, the claims are broadly drawn to the use of any maize line as a parent. See *In re Lindner*, 173 USPQ 356 (CCPA 1972) and *In re Grasselli*, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of non-obviousness should be commensurate with the scope of the claims.

Conclusion

7. No claims are allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith O. Robinson, Ph.D. whose telephone number is

Art Unit: 1638

571-272-2918. The examiner can normally be reached on Monday - Friday 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Keith O. Robinson, Ph.D.

June 5, 2006

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

